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ISSUE: Temperature Effects on Selected Pharmaceuticals

POINTS:

- The recommended storage conditions for selected pharmaceuticals are shown below. Every effort should be made to comply with the labeled storage temperature ranges. Some additional data regarding temperature excursions outside of the labeled ranges are provided, when available, to assist with product disposition decisions. **The provision of this data does not imply that mishandling of these pharmaceuticals is an acceptable practice**.

- Atropine 2mg Autoinjector 59 – 86^{0}F [15 – 30^{0}C]; protect from light; protect from freezing.
If frozen, injectors must be thawed and inspected for leakage before issuing. Freezing does not affect drug potency, but can damage the closures causing sterility compromise and loss of drug.
Atropine stored at the recommended temperatures remains potent for more than 5 years.
As temperatures rise above 86^{0}F (>30^{0}C) the rate of Atropine degradation increases.
Atropine stored at a constant temperature of 100^{0}F (38^{0}C) should be destroyed after 2 years.
Atropine stored at a constant temperature of 120^{0}F (49^{0}C) should be destroyed after 15 months.
When the constant storage temperature is 130^{0}F (54.5^{0}C) the Atropine should be destroyed after 12 months.
Finally, if the constant storage temperature reaches 150^{0}F (65.5^{0}C) the Atropine should be destroyed after 4 months.
Atropine exposed to temperatures above the 59 – 86^{0}F [15 – 30^{0}C] recommended range should be reported to your Service Medical Logistics Activity for possible potency testing in the FDA/DoD Shelf Life Extension Program.

- Pralidoxime Chloride (2-PAM) 600mg Autoinjector 59 – 86^{0}F [15 – 30^{0}C]; protect from freezing.
If frozen, injectors must be thawed and inspected for leakage before issuing. Freezing does not affect drug potency, but can damage the closures causing sterility compromise and loss of drug.
2-PAM stored at the recommended temperatures remains potent for more than 5 years.
As temperatures rise above 86^{0}F (>30^{0}C) the rate of degradation of 2-PAM increases.
2-PAM stored at a constant temperature of 95^{0}F (35^{0}C) should be destroyed after 1 year.
2-PAM stored at a constant temperature of 122^{0}F (50^{0}C) should be destroyed after 6 months.
Finally, if the constant storage temperature reaches 140^{0}F (60^{0}C) the 2-PAM should be destroyed after 6 weeks. Additionally, storage at 140^{0}F may result in injector needles protruding from the protective rubber sheaths; units should be inspected for this possible defect.
2-PAM exposed to temperatures above the 59 – 86^{0}F [15 – 30^{0}C] recommended range should be reported to your Service Medical Logistics Activity for possible potency testing in the FDA/DoD Shelf Life Extension Program.

- Diazepam 10mg Autoinjector (CANA) Below 104^{0}F [40^{0}C], manufacturer recommends 59 – 86^{0}F [15 – 30^{0}C]; protect from light; protect from freezing.
There is very little data available on the stability of CANA exposed to adverse high temperature environments. CANA stored at a constant temperature of 122^{0}F (50^{0}C) is stable for at least 6 months. CANA exposed to temperatures above the 59 – 86^{0}F [15 – 30^{0}C] recommended range should be reported to your Service Medical Logistics Activity for possible potency testing in the FDA/DoD Shelf Life Extension Program.
Do not allow CANA to freeze. Product will precipitate at low temperatures. If CANA has been frozen, it must be turned-in for destruction.

- Pyridostigmine Bromide 30mg tablets (PBT) Manufacturer recommends refrigeration 36 – 46^{0}F [2 – 8^{0}C] for longest potency duration; protect from light; protect from freezing.
At controlled room temperature, 59 – 86^{0}F [15 – 30^{0}C], potency is retained for 6 months. From >86 – 122^{0}F [>30 – 50^{0}C] PB tablet potency is retained for at least 3 months.
Tablets out of refrigeration, even in controlled environments must not be issued to Service members after 3 months.
Tablets exposed to temperatures above 122^{0}F [>50^{0}C] should not be dispensed since potency cannot be assured.

- Skin Exposure Reduction Paste Against Chemical Warfare Agents (SERPACWA) manufacturer recommends 59 – 86^{0}F [15 – 30^{0}C]; product is stable under extreme temperature conditions, however packaging may delaminate or leak. If product has been frozen or heated to extremely high temperatures it may still be used (when thawed) so long as packaging remains intact.
SERPACWA exposed to temperatures outside the recommended range of 59 – 86^{0}F [15 – 30^{0}C] should be reported to your Service Medical Logistics Activity for possible potency testing in the FDA/DoD Shelf Life Extension Program.

- Ciprofloxacin (Cipro) 500mg Tablets Below 86^{0}F [30^{0}C]; manufacturer recommends 59 – 86^{0}F [15 – 30^{0}C]
There are no constant high temperature storage data for Ciprofloxacin tablets.
Cipro exposed to high temperatures above the 59 – 86^{0}F [15 – 30^{0}C] recommended range should be reported to your Service Medical Logistics Activity for possible potency testing in the FDA/DoD Shelf Life Extension Program.

- Doxycycline (Doxy) 100mg Capsules/Tablets Below 104^{0}F [40^{0}C]; manufacturer recommends 59 – 86^{0}F [15 – 30^{0}C]; protect from light
There are no constant high temperature storage data for Doxycycline Capsules/Tablets. If any capsules have melted make the assumption the product in unsuitable for use.
Doxy exposed to high temperatures above the 59 – 86^{0}F [15 – 30^{0}C] recommended range should be reported to your Service Medical Logistics Activity for possible potency testing in the FDA/DoD Shelf Life Extension Program.

References:

1. USP DI, 21st Ed.; The United States Pharmacopoeial Convention, Inc., 2001
2. Manufacturers' product labeling
3. STI R&D Report RD-527
4. SRI Project #2653 Report #747
5. FDA/DoD Shelf Life Extension Program data on stability of Diazepam Autoinjectors